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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,178	07/08/2005	C. David Allis	00856-03	4003

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UNIVERSITY OF VIRGINIA PATENT FOUNDATION
250 WEST MAIN STREET, SUITE 300
CHARLOTTESVILLE, VA 22902

EXAMINER	
SZPERKA, MICHAEL EDWARD	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
06/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/542,178	ALLIS ET AL.	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11 and 14-21* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 14-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response and amendments received March 27, 2008 are acknowledged.

Claim 11 has been amended.

Claims 10, 12, and 13 have been canceled.

Claims 1-9, 11, and 14-21 are pending in the instant application.

Claims 1-9 and 14-21 stand withdrawn from consideration as being drawn to a nonelected invention. See 37 CFR 1.142(b) and MPEP § 821.03, for reasons of record set forth in the restriction requirement mailed June 18, 2007.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The rejection of claims 10 and 11 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicant's cancellation of claim 10 and applicant's amendments to claim 11 received March 27, 2008 which recite antibodies that bind the specific human ePAD of SEQ ID NO:1.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 10 and 11 under 35 U.S.C. 102(b) as being anticipated by Herr et al. (WO 01/53339, of record on the 3/31/06 IDS) has been withdrawn in view of applicant's claim amendments received March 27, 2008.

Specifically, claim 11 has been amended to recite the specific human polypeptide of SEQ ID NO:1, a polypeptide not disclosed by Herr et al., and claim 10 has been canceled.

6. The rejection of claim 10 under 35 U.S.C. 102(b) as being anticipated by Gossen et al. (WO 02/090531, of record on the 9/16/05 IDS) has been rendered moot by applicant's cancellation of said claim by amendment on March 27, 2008.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. The rejection of claims 10, 12, and 13 under 35 U.S.C. 103(a) as being unpatentable over Herr et al. (WO 01/53339, of record on the 3/31/06 IDS) in view of Gossen et al. (WO 02/090531, of record on the 9/16/05 IDS) has been rendered moot by applicant's cancellation of said claims as part of the response received March 27, 2008.

9. The following is a new ground of rejection necessitated by applicant's claim amendments received March 27, 2008.

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Herr et al. (WO 01/53339, of record on the 3/31/06 IDS) in view of Gossen et al. (WO 02/090531, of record on the 9/16/05 IDS).

Herr et al. disclose a novel mouse peptidylarginine deiminase (PAD) protein that is expressed only in gametes named MOP5 (see entire document, particularly the abstract and page 9). They further disclose that egg surface antigens, MOP5 included, are to be used in the production of antibodies, with such antibodies then being administered in contraceptive methods (see particularly lines 10-23 of page 4 and lines 10-19 of page 7). Contraceptive methods are disclosed which comprise passive immunization wherein preformed antibodies that bind MOP5 are administered to a female subject (see particularly lines 11-28 of page 16). The antibodies and contraceptive methods disclosed by Herr et al. are disclosed as comprising human and humanized antibodies, and the methods are disclosed as being suitable for use in humans (see particularly lines 11-17 of page 1, lines 10-19 of page 7, and pages 14-18). This disclosure differs from the claimed invention in that Herr et al. do not disclose the human PAD protein of SEQ ID NO:1.

Gossen et al. disclose the sequence of human PAD6, a novel peptidylarginine deiminase that is only expressed in oocytes (see entire document, particularly the abstract, page 2, lines 21-27 of page 16 and Figure 4). They further disclose contraceptive methods which comprise the administration of PAD6 inhibitors to females (see entire document, particularly the abstract and lines 12-17 of page 7). Note that while PAD6 disclosed by Gossen et al. does not comprise all of the amino acid sequence information of SEQ ID NO:1 of the specification (i.e. PAD6 is smaller), the sequences do align over the entire length of PAD6 such that any antibody which binds

an epitope of PAD6 would also bind SEQ ID NO:1 due to sequence identity (see sequence alignment of record with the 10/24/07 office action). Note further that this sequence identity means that PAD6 comprises a fragment of SEQ ID NO:1.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the human PAD6 sequence disclosed by Gossen et al. for MOP5 in the contraceptive methods disclosed by Herr et al. Motivation to do so comes from the fact that MOP5 and PAD6 are both egg-specific peptidylarginine deiminase proteins, the fact that both Gossen et al. and Herr et al. disclose that PAD inhibitors are to be used in contraceptive methods to reduce female fertility, and the fact that antibodies that bind a human protein are more suitable for administration to human patients since identification of crossreactive epitopes between murine and human homologues do not need to be identified or relied upon to achieve therapeutic efficacy.

11. No claims are allowable.

12. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
Primary Examiner
Art Unit 1644

/Michael Szperka, Ph.D./
Primary Examiner, Art Unit 1644